DETAILED ACTION

Status of Application

1. The response filed December 18, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 13-14 have been amended.

   b. Claim 18 has been added.

2. Claims 1-18 are pending in the case.

3. Claims 13-18 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for free base of indapamide and the hemihydrate form, it does not reasonably provide enablement for all hydrates. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Pursuant to In re Wands, 8 USPQ2d 1400, factors such as:

(1) The nature of the invention and (2) the breadth of the claims:

The claim is drawn to indapamide or a hydrate thereof. The specification, while enabling for the free base and the Merck Index enables for the hemihydrate form, it does not reasonably provide enablement for all its possible hydrates.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Vippagunta et al. (Advanced Drug Delivery Reviews 48 (2001) 3-26) teaches that predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Certain molecular shapes and features favor the formulation of crystals without solvent. No computer programs are currently available for predicting the crystal structures of hydrates and solvates and generalizations cannot be made for a series of related compounds. [Page 18, 3.4]

Thereby resulting in high unpredictability in the art.

(5) The relative skill of those in the art:

The degree of skill in the art is high, generally one with a Masters of PhD in the chemical arts.

(6) direction or guidance:

None is seen in the specification. Not all solvents can form solvates with all compounds; there is no process present in the specification producing a final product that is a solvate;

(7) presence or absence of working examples:

There is no example of a hydrate in the present case and the Merck Index only address for the hemihydrate, which does not allow one to ascertain the entirely of the claimed genus, the scope, nor how to make the genus claimed;

(8) quantity of experimentation needed:

Considering the state of the art as discussed by the references above, particularly with regards to the teaching of Vippagunta et al. and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make the invention commensurate in the scope of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 13-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guez et al. (WO 99/25374) in view of Eyjolfsson (WO 03/059388) and Pharmaceutical Dosage Forms: Tablets.

It is noted that Guez et al (U.S. Pat. 6653336) will be used as the translation for Guez et al. (WO 99/25374) and all references will be to the U.S. Pat.

Guez et al. teaches the combination of an angiotensin-converting enzyme inhibitor (ACE or CEI) and a diuretic in a pharmaceutical composition. Guez teaches the benefits of the combination and the preferred CEI particularly is perindopril and its salts. The preferred diuretic is indapamide and hydrochlorothiazide and their salts, more particularly indapamide. Examples teach the combination of perindopril and indapamide in pharmaceutical compositions with excipients including microcrystalline cellulose. Guez teaches the inclusion of excipients, binders, diluents, stabilizing agents, and other desirable components (Abstract, Col. 2 line 55-62, Col. 3 line 11-Col. 4 line 50). It is known in the art that microcrystalline cellulose is a moisture control agent and the commercially available products (such as Avicel®PH-101) generally have moisture contents of less than 5% (see Signet sheets). Guez also teaches several composition forms including instantaneous and delayed release. It is noted that the limitation of the DKP content at 3 week storage at 50°C in a closed container as written, would be intrinsic to a composition with perindopril, microcrystalline cellulose, anhydrous lactose, at least one inorganic carbonate, and optionally other components. As a result, when the composition limitations are met the properties would intrinsically be met as any

component that materially affect the composition would have to be present in the claim to be commensurate in scope.

Guez et al. does not expressly teach the use of anhydrous lactose, carbonate, or a molar ratio of 1 to 0.1-0.9 for perindopril to inorganic carbonate. Guez does teach the inclusion of excipients such as stabilizing agents in the formulation. Guez also teaches the use of pharmaceutically acceptable excipients exemplifying lactose.

Pharmaceutical Dosage Forms teaches that lactose forms are the most widely use diluent in tablet formulations and has good stability in combination with most drugs whether in hydrous or the anhydrous form (functional equivalents). Pharmaceutical Dosage Forms also teaches that anhydrous lactose has most of the advantages of hydrous lactose without the browning (reactivity of the Maillard reaction) along with additional advantages (e.g. good friability, lack of sticking and capping) such as good crushing strengths (Figure 5) over hydrous lactose.

Eyjolfsson teaches the inclusion of components including of carbonates, particularly alkali or alkaline-earth metal carbonates produce useful and stable ACE inhibitor formulations. The ACE inhibitors taught include perindopril and the combination of diuretics. Eyjolfsson teaches a preferred embodiment of the amount of carbonate to at least the equivalent of the active. However, the general teaching of Eyjolfsson is to the inclusion of carbonates for the production of stable ACE inhibitor formulations and claims a composition with an ACE inhibitor including perindopril, at 0.5-50wt.%, and the alkali or alkaline earth metal carbonate at 5-90% encompassing ratios in the preferred embodiment such as 1:1 and ratios beyond the preferred embodiment, such as 1:0.5

and 1:0.9 (see document, specifically Abstract, Page 2 line 5-16, page 3 line 24-25, Page 4 line 10-15, Claims 1-2, 4, 11).

It would have been obvious to one of skill in the art to use any form of lactose including anhydrous lactose as the forms are functionally equivalent depending on the desired properties of the diluent such as friability and crushing strength, stability of the drug, and desired final properties of the tablet. It would have been obvious and desirable to use anhydrous lactose as it possessed most of the desired properties of the hydrous lactose without the undesirable properties such as browning (Maillard reaction).

It also would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include carbonates and optimize the molar ratio to the ACE inhibitor, as suggested by Eyjolfsson, and produce the instant invention.

It would have been obvious to incorporate components such as the carbonates of Eyjolfsson for ACE inhibitors like perindopril, as Eyjolfsson teaches the inclusion of carbonates improves the stabilization of ACE inhibitor and Guez teaches the inclusion of components for increased stabilization of a formulation. It would have been obvious to one of skill in the art to optimize the amount carbonate as the general teaching encompasses ratios below 1:1 as presented in the claims and the specification to affect the amount of stabilization for a pharmaceutical formulation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation as the adjustment of particular conventional working conditions, such as determining a suitable effective dosage in

combination with other component ranges to affect stability (more/less stability, more/less carbonate), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan to yield the desired properties in the composition.

One of ordinary skill in the art would have been motivated to do this because combining components that would provide a more stable composition and yield an increasingly effective and desirable product with better shelf life is desirable.

9. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guez et al. (WO 99/25374) in view of Eyjolfsson (WO 03/059388) and Pharmaceutical Dosage Forms: Tablets , as applied to claim 13 and 14 above, in view of www.signetchem.com, and further in view of Cooper et al. (U.S. Pat. Publication 2003/0137067).

The teachings of Guez et al. in view of Eyjolfsson and Pharmaceutical Dosage Forms: Tablets are addressed above.

Guez et al. in view of Eyjolfsson and Pharmaceutical Dosage Forms: Tablets do not expressly teach the use of microcrystalline cellulose with a moisture content of 0.3-1.5% by weight. Guez does teach the inclusion of microcrystalline cellulose and the diuretic indapamide. Guez also teaches several composition forms including instantaneous and delayed release.

www.signetchem.com teaches that a number of commercial microcrystalline celluloses with different properties, size, and forms were readily available for purchase

and use in 2002 for one of skill in the art at the time of the invention to produce the product properties desired.

Reduction of particle size for poorly soluble agents to improve their bioavailability is known in the art as evidenced by Cooper et al. which teaches the reduction of particle size for poorly soluble agents as nanoparticles to improve their bioavailability is known (paragraph 3). A listing of several known formulations is presented (e.g. paragraph 4-6). Cooper also addresses that other drugs such as ACE inhibitors and diuretics can be in non-nanoparticle sizes or in nanoparticulate sizes is they are poorly soluble addressing that the formation of nanoparticulate sizes for ACE inhibitors and diuretics which are poorly soluble are known are known in the art to improve bioavailability (paragraph 77, 81, 85). Cooper teaches that modification of known active agents in various particle sizes with other actives in various particle sizes to obtain immediate-release (e.g. particle size less than about 1000nm, paragraph 95) and controlled-release forms such as larger micronized sizes (e.g. less than about 70 microns-paragraph 96) for slower release is known in the art and within the skill of one in the art. Cooper addresses that making nanoparticulate actives are known in the art (paragraph 47) and that formation of the compositions ca be any conventional means, and teaches forms for immediate and controlled release of nanoparticles and microparticles (paragraph 46-56). The actives include cardiovascular agents, cardiac ionotropic agent, diuretic, and antihypertensive agents (Paragraph 35-37, 64-67, 94-102).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize any commercially available microcrystalline

celluloses (e.g. Avicel®PH-112) and to modify the particle size of the drugs based on desired release rate, in the composition taught by Guez, as suggested by www.signetchem.com and Cooper, and produce the instant invention.

It would have been obvious at the time of the invention to purchase any appropriate microcrystalline cellulose such as Avicel®PH-112 to use and to modify the composition taught by Guez in view of Eyjolfsson as needed to arrive at a final product with the desired properties. It would have also been obvious to modify the teachings presented by Guez including particle size, to create products with any number of specialized forms and dissolutions/solubility such as nanoparticle sizes (less than 1 micron, e.g. immediate release) or micron sizes (e.g. delayed release, etc.) depending the on the drug release profile and form desired which is well within the skill of one in the art.

One of ordinary skill in the art would have been motivated to do this because it is more cost effective to purchase a commercial product than to produce the microcrystalline cellulose yourself, and the commercial product is desirable as it had consistent properties and uniformity in the mixture. One would have been motivated to modify the components (microcrystalline cellulose, particle size, etc.) to provide a number of materials that would be uniquely suited for the product use desired such as immediate release or controlled release compositions which are modifiable base on the components and/or particle size to yield the desired drug release profile.

10. Claims 13-14, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (U.S. Pat. 4743450) in view of Guez et al. (WO 99/25374).

It is noted that Guez et al (U.S. Pat. 6653336) will be used as the translation for Guez et al. (WO 99/25374) and all references will be to the U.S. Pat.

Harris et al. teaches a stable ACE inhibitor composition comprising at least one ACE inhibitor, a saccharide, and a metal-containing stabilizer (Abstract, Col. 1 line 5-8). Any ACE inhibitor can be used in the composition with well-known antihypertensive properties including enalapril, quinapril (Col. 2 line 5-10, 32-34). The drug content is about 1 to about 70%, preferably from about 1% to about 25% (Col. 2 line 39-41), the metal stabilizer such as the carbonates are present between about 1% to 90% of the composition (Col.3 line 24-44) wherein any amount which will effectively retard/prevent degradation of the ACE inhibitor used, and the saccharide components are present from about 5% to about 90% (Col. 3 line 45-60).

The metal stabilizers include magnesium, calcium, and sodium salts with borates, silicates, and carbonates; the carbonates are preferred and mixtures are operable. The saccharides include mannitol, lactose, other sugars, and mixtures thereof. Forms include tablets and capsules with optional excipient that can be used in the compositions such as lubricants, binders, and other additives. Harris also teaches that other active agents including diuretics such as hydrochlorothiazide, can by incorporated with the ACE inhibitors (see full document, Col. 2 line 59-68).

Examples are taught with the inclusion of the ACE inhibitor, metal stabilizer, and saccharide. An example with an ACE inhibitor (quinapril), saccharide (anhydrous lactose), and microcrystalline cellulose is also presented without the metal stabilizer (Example C) wherein the improved stabilization of the metal carbonate is taught. The

molar ratios for the ACE inhibitor for the examples include 0.193 (example A) and 0.101 (Example D). It is noted that the limitation of the DKP content at 3 week storage at 50°C in a closed container as written, would be intrinsic to a composition with perindopril, microcrystalline cellulose, anhydrous lactose, at least one inorganic carbonate, and optionally other components. As a result, when the composition limitations are met the properties would intrinsically be met as any component that materially affect the composition would have to be present in the claim to be commensurate in scope.

Harris et al. does not expressly teach the claimed range of molar ratios for the ACE inhibitor to the carbonate, or an example with the ACE inhibitor with microcrystalline cellulose, anhydrous lactose, at least one inorganic carbonate.

Harris does however does teach ACE inhibitor compositions with carbonates, saccharides such as lactose, and other excipients. Harris also teaches molar ratios for the ACE inhibitor for the examples include 0.193 (example A) and 0.101 (Example D) which are within the claimed range. Harris also presents an example with an ACE inhibitor, microcrystalline cellulose, and anhydrous lactose; addressing the benefits of compositions that included the metal stabilizer in the formulation (i.e. carbonate, e.g. Example A). Harris also teaches that the ACE inhibitor content is from about 1 to about 70%, preferably from about 1% to about 25% (Col. 2 line 39-41) and the carbonates (metal stabilizer) are present from about 1% to 90% of the composition (Col.3 line 24-44) wherein Harris expressly addresses that the amount of carbonate should effectively retard/prevent degradation of the ACE inhibitor be used.

It would also be obvious to one of skill in the art to incorporate the carbonate to Example C in the taught ranges and in the exemplified ratios, as the teachings of Harris are to stabilized formulations (e.g. title, abstract, claims) and Harris expressly teaches the Example C formulation where the stabilizing element (carbonate) was removed to show the benefits of the carbonate; wherein it is implicit that to stabilize the tablet formulation, the carbonate would be incorporated to produce a stable formulation in the taught percentages and ratios, as a stabilized tablet is very desirable.

It also would have been obvious to one of skill in the art to optimize the amount carbonate to affect the amount of stabilization for a pharmaceutical formulation, as the general teaching of Harris (ACE inhibitor-about 1 to about 70% preferably about 1% to about 25%; carbonates- about 1% to 90%) encompasses ratios below 1:1 and present examples with ACE inhibitor/carbonate ratios of 0.193 (example A) and 0.101 (Example D) that are within the range of claim 14, and Harris expressly addresses that the amount of carbonate should effectively retard/prevent degradation of the ACE inhibitor be used.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation as the adjustment of particular conventional working conditions, such as determining a suitable effective amount or ratio within the taught component ranges, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan to yield the desired properties in the composition. Optimization of parameters is routine practice which would be obvious for one of skill in the art to

employ and would reasonable expect success. One of ordinary skill in the art would have been motivated to do this because combining components that would provide a more stable composition and yield an increasingly effective and desirable product with better shelf life is desirable. Thus, absent some demonstration of unexpected results/criticality from the taught parameters in the art, this optimization of ingredient amount and ratio would have been obvious at the time of invention.

Harris et al. does not expressly teach the inclusion of the ACE inhibitor perindopril. Harris does teach an ACE inhibitor composition and the inclusion of other drugs including diuretics such as hydrochlorothiazide.

Guez et al. teaches that quinapril, enalapril, ramipril, perindopril, and indolapril are functionally equivalent ACE inhibitors. Guez et al. teaches the combination of an angiotensin-converting enzyme inhibitor (ACE or CEI) and a diuretic in a pharmaceutical composition is known as evidenced by Harris (Col. 2 line 55-63). Guez also teaches the benefits of the combination with the preferred ACE inhibitor being perindopril and its salts, and the preferred diuretic is indapamide and hydrochlorothiazide and their salts, wherein they are functional equivalents and the particularly preferred diuretic is indapamide (Col. 2 line 64-Col. 3 line 46). Guez also addresses compatibility of these actives with excipients such as microcrystalline cellulose (Example 1-2), binders, and stabilizers (Col. 3 line 65- Col. 4 line 5).

It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate perindopril in the composition and substitute perindopril for quinapril in the examples, as suggested by Guez, and produce the instant

invention. It would be obvious to incorporate perindopril in the composition as Harris teaches the composition for ACE inhibitors encompassing perindopril, and substitute one ACE inhibitor for another such as perindopril for quinapril in the examples such as a stabilized Example C as addressed above, as they are functional equivalent ACE inhibitors and one of ordinary skill in the art would have been motivated to do this because it is desirable for manufacturers to have functionally equivalent choices to depending on the pricing, availability, or desired properties of the ACE inhibitor used to produce the final product. This same rational as addressed above and below, would also apply to functionally equivalent diuretics such as indapamide and hydrochlorothiazide.

11. Claim 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (U.S. Pat. 4743450) in view of in view of Guez et al. (WO 99/25374) as applied to claims above, in view of www.signetchem.com.

The teachings of Harris and Guez are addressed above including in the inclusion of excipients including modified cellulose derivatives such as microcrystalline cellulose in Example C, the known combination of ACE inhibitors and diuretics (e.g. ACE inhibitors and hydrochlorothiazide, perindopril and hydrochlorothiazide, perindopril and indapamide), and the functional equivalence of hydrochlorothiazide and indapamide.

Harris in view of Guez do not expressly teach do not expressly teach microcrystalline cellulose to have a moisture content of 0.3-1.5% by weight.

Harris in view of Guez does address the combination of ACE inhibitors with diuretics (Harris and Guez). Harris recites the diuretic hydrochlorothiazide and

exemplifies quinapril. Guez addresses the functional equivalence of the ACE inhibitors perindopril and quinapril with a preference for perindopril, the functional equivalence of the diuretics hydrochlorothiazide and indapamide with a preference for indapamide, and the preferred combination of indapamide and perindopril. As addressed above, it would be obvious to one of skill in the art to substitute one functionally equivalent active such as indapamide for hydrochlorothiazide as Guez teaches their equivalence where it is desirable to have equivalents, along with the combination of perindopril with indapamide wherein the inclusion of the diuretic is expressly taught by Harris and the combination is known as addressed by Guez. One would be motivated to combine the two as the benefits are known and addressed by Guez (e.g. address the disorders at an arteriolar and capillary level).

www.signetchem.com teaches that a number of commercial microcrystalline celluloses with different properties, size, and forms were readily available for purchase and use in 2002 for one of skill in the art at the time of the invention to produce the product properties desired.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize any commercially available microcrystalline celluloses (e.g. Avicel®PH-112) in the composition, as suggested by www.signetchem.com, and produce the instant invention.

It would have been obvious at the time of the invention to purchase any appropriate commercially available microcrystalline cellulose such as Avicel®PH-112 to

use for the composition to arrive at a final product with the desired properties such as the degree of moisture, size, and grade.

One of ordinary skill in the art would have been motivated to do this because it is more cost effective to purchase a commercial product than to produce the microcrystalline cellulose yourself, and the commercial product is desirable as it had consistent properties, uniformity in the mixture, and ease of use.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harris et al. (U.S. Pat. 4743450) in view of Guez et al. (WO 99/2537442196) and www.signetchem.com, in view of Batycky et al. (U.S. Pat. Pub. 2003/0129250).

The teaching of Harris, Guez, and www.signetchem.com are addressed above.

Harris in view of Guez and www.signetchem.com do not expressly teach do not expressly teach the indapamide particle size.

Batycky et al. teaches that modification of poorly soluble drugs through reduction of the particle size and spray draying of poorly soluble actives improve their dissolution in oral dosage form delivery by 2-fold to about 25-fold (Abstract). Batycky addressed that general techniques to address poor solubility of drug such as particle modification (e.g. particle size reduction) are known in the art (paragraph 3). Batycky teaches pharmaceutical compositions comprising poorly soluble drug particles such as indapamide (claimed-claim 4) in reduced particle sizes including about 20nm to about 500nm have improving poor drug solubility between about 2-fold to about 25-fold (claims 1-29).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the particle size of indapamide within the range of about 20nm to about 500nm, as suggested by Batycky, and produce the instant invention. It would have been obvious to one of skill in the art to adjust the particle size of indapamide as it is known poorly soluble drug and particle size reduction to improve solubility is well known in the art. It would have been obvious to use the indapamide drug particle of Batycky with particle sizes from about 20nm to about 500nm as it has improved drug solubility between about 2-fold to about 25-fold.

One of ordinary skill in the art would have been motivated to do this because it is desirable to improve the solubility of poorly soluble drugs such as indapamide particularly as Batycky's particles have improved solubility of about 2-fold to about 25-fold for improve therapeutic delivery.

Response to Arguments

13. Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for free base of indapamide, does not reasonably provide enablement for all hydrates.

Applicant's arguments filed 12/18/2009 have been fully considered but they are not persuasive. Applicant asserts that hydrate of indapamide is known in the art before the filing date as evidenced by the Merck Index submitted. This is persuasive for the hemihydrate form but not persuasive for all forms of hydrates of indapamide encompassed by the claims as written. The unpredictability of the art as addressed previously and restated above, for all the hydrate forms encompassed by the claims is

not enabled without a reasonable showing of how to create the hydrate forms encompassed by the broad term of the claims beyond the single hemihydrate presented in the Merck Index as a single hydrate is not a representative number for an enabling disclosure for all the hydrates encompassed by the claims.

Accordingly, the rejection is maintained.

14. Applicant's arguments filed 12/18/2009 in regards to Cooper et al. (U.S. Pat. Publication 2003/0137067) is directed to that Cooper is cited for teaching regarding polycosanol nanoparticulates for control-release forms and that perindopril is not mentioned. This is not persuasive as Cooper is used to show the knowledge of one of skill in the art in that reduction of particle size of poorly soluble drugs improves bioavailability and modification of particle sizes of these types of agents to formulate forms with immediate release by forming a nanoparticle (less that one micron) and sustained/control release (e.g. less than 70microns-paragraph 96) is not only known in the art as taught by Cooper, but within the skill of one in the art. Cooper addresses that this is applicable to many drug classes including diuretics and cardiovascular drugs. Applicant's assertion that perindopril is not expressly listed is not persuasive as the claim is to indapamide and the general teaching is for poorly soluble drugs in these classes to be micronized for improved solubility to be known in the art wherein it is obvious to one of skill in the art absent a showing of unexpected results to micronized the poorly soluble drugs which indapamide and perindopril are known as evidence by the art above, and optimize the size to attain the desired bioavailability.

Conclusion

15. Claims 13-18 are rejected.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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